

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES, INC., FOREST)	
LABORATORIES HOLDINGS, LTD. &)	
ROYALTY PHARMA COLLECTION)	
TRUST,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. 13-1605 (SLR)
)	
MYLAN INC. and)	
MYLAN PHARMACEUTICALS INC.)	
)	
Defendants.)	

**FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD.,
AND ROYALTY PHARMA COLLECTION TRUST’S REPLY TO COUNTERCLAIMS
OF MYLAN INC., AND MYLAN PHARMACEUTICALS INC.**

Plaintiffs and Counterclaim Defendants Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd. (collectively, “Forest”), and Royalty Pharma Collection Trust (all collectively, “Plaintiffs”) by and through the undersigned counsel, answers as follows the counterclaims asserted by Mylan Inc. and Mylan Pharmaceuticals Inc. (collectively, “Mylan”) in its Answer, Defenses, and Counterclaims. (D.I. 10 at 20.) Plaintiffs believe that no reply to Mylan’s Answer and Defenses is required, but to the extent Mylan contends that such a reply is required, Plaintiffs deny the allegations in Mylan’s defenses.

COUNTERCLAIMS

COUNTERCLAIM:

1. Mylan Pharmaceuticals Inc. (“Mylan Pharms.”) is a corporation organized under the laws of the State of West Virginia, having an office and place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

REPLY: On information and belief, Plaintiffs admit the allegations in Paragraph 1.

COUNTERCLAIM:

2. Mylan Inc. is a corporation organized under the laws of the State of Pennsylvania, having an office and place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

REPLY: On information and belief, Plaintiffs admit the allegations in Paragraph 2.

COUNTERCLAIM:

3. On information and belief, and based on Forest's allegations, Counterclaim defendant Forest Laboratories, Inc. ("Forest Labs.") is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York, 10022.

REPLY: Admitted.

COUNTERCLAIM:

4. On information and belief, and based on Forest's allegations, Counterclaim defendant Forest Laboratories Holdings, Ltd. is an Irish corporation having a principal place of business at Columbia House, 1 Victoria Street, Hamilton HM11, Bermuda (referred herein, together with Forest Labs, as "Forest")

REPLY: Admitted.

COUNTERCLAIM:

5. On information and belief, and based on Forest's allegations, Counterclaim defendant Royalty Pharma Collection Trust ("Royalty Pharma") is a Delaware trust having a principal place of business at Rodney Square North, 1100 North Market Street, Wilmington, Delaware 19890-0001.

REPLY: Admitted.

COUNTERCLAIM:

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

REPLY: Paragraph 6 states legal conclusions for which no response is required. To the extent a response is required, Plaintiffs admit that Mylan purports to counterclaim for declaratory judgment pursuant to the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.* Plaintiffs otherwise deny the allegations of Paragraph 6.

COUNTERCLAIM:

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a).

REPLY: Paragraph 7 states legal conclusions for which no response is required. To the extent a response is required, Plaintiffs do not contest that subject matter jurisdiction is proper in this judicial district for the purposes of this action only. Plaintiffs admit that an actual controversy exists between Mylan and Plaintiffs concerning the validity and/or infringement of only United States Patent Nos. 6,602,911 (“the ’911 patent”); 7,888,342 (“the ’342 patent”), and 7,994,220 (“the ’220 patent”). Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the ’110 patent because (1) Plaintiffs did not assert the ’110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the ’110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the ’110 patent. Plaintiffs otherwise deny the allegations of Paragraph 7.

COUNTERCLAIM:

8. This Court has personal jurisdiction over Forest because Forest has availed itself of the rights and privileges, and subjected itself to the jurisdiction, of this forum by suing Mylan in this District, and/or because Forest conducts substantial business in this District.

REPLY: Plaintiffs do not contest that this Court has personal jurisdiction over Mylan’s Counterclaims concerning only the ’911, ’342 and ’220 patents. Plaintiffs admit that Forest conducts business in the District of Delaware. Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the ’110 patent because (1) Plaintiffs did not assert the ’110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the ’110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its

Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 8.

COUNTERCLAIM:

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

REPLY: Plaintiffs do not contest that venue is proper in this judicial district for the purposes of this action only. Plaintiffs otherwise deny the allegations of Paragraph 9.

COUNTERCLAIM:

10. Upon information and belief, and based on the FDA's website, Cypress Bioscience is the current holder of New Drug Application ("NDA") No. 022256 for the manufacture and sale of Savella[®] (Milnacipran Hydrochloride) tablets.

REPLY: Plaintiffs admit that the United States Food and Drug Administration's ("FDA") "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") lists that Cypress Bioscience is the holder of New Drug Application ("NDA") No. 022256 for milnacipran hydrochloride tablets, sold in the United States as Savella[®]. Plaintiffs otherwise deny the allegations of Paragraph 10.

COUNTERCLAIM:

11. Upon information and belief, Counterclaim-defendant Forest Labs. markets Milnacipran Hydrochloride tables in 12.5 mg, 25 mg, 50 mg, and 100 mg dosage strengths in the United States under the trade name Savella[®] through its subsidiary Forest Pharmaceuticals, Inc. According to the United States Food and Drug Administration's ("FDA") website, Savella[®] was approved by FDA on January 14, 2009.

REPLY: Plaintiffs admit that Forest is the exclusive distributor of Milnacipran Hydrochloride tablets in 12.5 mg, 25 mg, 50 mg, and 100 mg dosage strengths in the United States, which are sold under the brand name Savella[®]. Plaintiffs admit that the FDA's website indicates that

Savella[®] was approved by the FDA on January 14, 2009. Plaintiffs otherwise deny the allegations of Paragraph 11.

COUNTERCLAIM:

12. On information and belief, and based on Forest's allegations, Counterclaim defendant Royalty Pharma is listed as the purported owner of record and the purported assignee of U.S. Patent Nos. 6,602,911 (the '911 Patent"); 7,888,342 (the '342 Patent"); 6,992,110 (the "'110 Patent") and 7,994,220 (the '220 Patent") (collectively, the "Asserted Patents").

REPLY: Plaintiffs admit that Royalty Pharma Collection Trust is listed as the assignee of record of the '911 Patent, the '342 Patent, and the '220 Patent according to the PTO's Patent Assignment Abstracts of Title. Plaintiff Forest is the exclusive licensee of the '911, '342, and '220 patents and is the exclusive distributor of tablets containing 12.5 mg, 25 mg, 50 mg, and 100 mg of the active ingredient milnacipran hydrochloride in the United States, which are sold under the brand name Savella[®]. Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 12.

13. Counterclaim-Defendants have informed the FDA of the unexpired Asserted Patents with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use of sale of Milnacipran Hydrochloride tablets. The Asserted Patents are listed by the FDA in its publication "*Approved Drug Products with Therapeutic Equivalence Evaluations*," commonly referred to as the "Orange Book" for the NDA, under 21 U.S.C. § 355(j)(7).

REPLY: Paragraph 13 states legal conclusions for which no response is required. To the extent a response is required, Plaintiffs admit that the '911, '342, and '220 patents are listed in the

Orange Book in connection with NDA 022256. The legal effect of listing such patents is specified by 21 U.S.C 355(j). Plaintiffs otherwise deny the allegations of Paragraph 13.

COUNTERCLAIM:

14. Listing the Asserted Patents in the Orange Book, is a purported representation to the world that these patents cover Milnacipran Hydrochloride tablets, and that an infringement suit could be alleged against any generic ANDA applicant, including Mylan, that attempts to seek approval for, and market, a generic version of Milnacipran Hydrochloride tablets before the patents' expiration.

REPLY: Paragraph 14 states legal conclusions for which no response is required. To the extent a response is required, Plaintiffs admit that the '911, '342 and '220 patents are listed in the Orange Book in connection with NDA 022256. The legal effect of listing such patents is specified by 21 U.S.C 355(j). Plaintiffs otherwise deny the allegations of Paragraph 14.

COUNTERCLAIM:

15. Mylan Pharms. holds Abbreviated New Drug Application ("ANDA") No. 205-367 for Milnacipran Hydrochloride tablets in 12.5, 25, 50 and 100 mg strengths.

REPLY: On information and belief, Plaintiffs admit that Mylan Pharms. submitted ANDA No. 205-367. Plaintiffs otherwise deny the allegations of Paragraph 15.

COUNTERCLAIM:

16. Mylan Pharms. filed a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") certifying that each of the Asserted Patents listed in the Orange Book is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, importation, or sale of Milnacipran Hydrochloride tablets ("Proposed Product") as covered by ANDA No. 205-367. In accordance with 35 U.S.C. § 355(j)(2)(B)(i) and (ii), Mylan Pharms. mailed Cypress Biosciences, Inc., Royalty Pharm, and Royalty Pharma Collection Trust, a notice that it had filed such a Paragraph IV Certification and provided the factual and legal bases for that Certification.

REPLY: Plaintiffs admit that Mylan sent or caused to be sent to Plaintiffs a letter dated August 27, 2013 that states that Mylan Pharms.' ANDA No. 205-367 included a Paragraph IV Certification directed to the '911, '342, and '220 patents alleging claims 1-7 of the '911 patent,

claims 1-10 of the '342 patent, and claims 1-7 of the '220 patents are invalid and not infringed. On information and belief, Plaintiffs admit that Mylan mailed Cypress Biosciences, Inc., Royalty Pharm, and Royalty Pharma Collection Trust a notice that it had filed such a Paragraph IV Certification. Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 16.

COUNTERCLAIM:

17. In connection with the giving notice to Cypress Biosciences, Inc., Royalty Pharm, and Royalty Pharma Collection Trust of its Paragraph IV Certification, Mylan Pharms. provided an offer of confidential access to its ANDA in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(I)(cc) and (III).

REPLY: Plaintiffs admit that the letter dated August 27, 2013 contained terms of an offer of confidential access to certain information from Mylan's ANDA. Plaintiffs otherwise deny the allegations of Paragraph 17.

COUNTERCLAIM:

18. On September 23, 2013, Forest sued Mylan in this district alleging infringement of the Asserted Patents based on Mylan's ANDA No. 205-367. Accordingly, there is an actual, substantial and continuing justiciable case and controversy between Forest and Mylan regarding the Asserted Patents, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

REPLY: Paragraph 18 states legal conclusions for which no response is required. To the extent a response is required, Plaintiffs admit that on September 23, 2013, Plaintiffs sued Mylan in this district alleging infringement of the '911, '342, and '220 patents based on Mylan's ANDA No. 205-367. Plaintiffs admit that an actual and justiciable controversy exists between Mylan and Plaintiffs concerning the infringement and validity of the '911, '342, and '220 patents. Plaintiffs

deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 18.

COUNTERCLAIM:

19. Mylan is statutorily entitled to bring and maintain this action for declaratory judgment pursuant to the Medical Modernization Act in order to obtain patent certainty, in accordance with 21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

REPLY: Paragraph 19 states legal conclusions for which no response is required. To the extent a response is required, Plaintiffs admit that there is a sufficient case or controversy between the parties sufficient for Mylan's declaratory judgment action concerning the '911, '342, and '220 patents. Plaintiffs otherwise deny the allegations of Paragraph 19.

COUNTERCLAIM:

20. As a result of any exclusion of Mylan from the marketplace, Mylan and the public will be irreparably harmed by the potential indefinite delay in the market entry and availability of lower-priced Milnacipran Hydrochloride tablets.

REPLY: Denied.

COUNTERCLAIM:

21. This case is exceptional pursuant to 35 U.S.C. § 285 and Mylan is entitled to its reasonable attorney fees pursuant to that statute.

REPLY: Denied.

COUNTERCLAIM:

22. Mylan re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Defenses and Counterclaims, above, as if fully set forth herein.

REPLY: No response is required to the general reallegation and incorporation by reference of Paragraphs 1-21 of the Counterclaims. To the extent a response is required, Plaintiffs hereby incorporate by reference their responses to Paragraphs 1-21.

COUNTERCLAIM:

23. The manufacture, use, sale, offer for sale, or importation of Milnacipran Hydrochloride tablets that are the subject of Mylan Pharms.' ANDA No. 205-367 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '911 Patent.

REPLY: Denied.

COUNTERCLAIM:

24. Mylan and Forest have adverse legal interests, and there is a substantial controversy between Mylan and Forest of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '911 Patent. Therefore, a present, genuine, and justiciable controversy exists between Mylan and Forest regarding, *inter alia*, the infringement of any valid or enforceable claim of the '911 Patent.

REPLY: Plaintiffs admit that Mylan and Forest have adverse legal interests and that a substantial controversy exists between Mylan and Plaintiffs concerning the infringement of the '911 patent. Plaintiffs deny the remaining allegations of Paragraph 24.

COUNTERCLAIM:

25. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Milnacipran Hydrochloride tablets that are the subject of Mylan Pharms.' ANDA No. 205-367 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '911 Patent.

REPLY: Denied.

COUNTERCLAIM:

26. Mylan re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Defenses and Counterclaims, above, as if fully set forth herein.

REPLY: No response is required to the general reallegation and incorporation by reference of Paragraphs 1-25 of the Counterclaims. To the extent a response is required, Plaintiffs hereby incorporate by reference their responses to Paragraphs 1-25.

COUNTERCLAIM:

27. The manufacture, use, sale, offer for sale, or importation of Milnacipran Hydrochloride tablets that are the subject of Mylan Pharms.' ANDA No. 205-367 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '342 Patent.

REPLY: Denied.

COUNTERCLAIM:

28. Mylan and Forest have adverse legal interests, and there is a substantial controversy between Mylan and Forest of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '342 Patent. Therefore, a present, genuine, and justiciable controversy exists between Mylan and Forest regarding, *inter alia*, the infringement of any valid or enforceable claim of the '342 Patent.

REPLY: Plaintiffs admit that Mylan and Forest have adverse legal interests and that a substantial controversy exists between Mylan and Plaintiffs concerning the infringement of the '342 patent. Plaintiffs deny the remaining allegations of Paragraph 28.

COUNTERCLAIM:

29. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Milnacipran Hydrochloride tablets that are the subject of Mylan Pharms.' ANDA No. 205-367 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '342 Patent.

REPLY: Denied.

COUNTERCLAIM:

30. Mylan re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Defenses and Counterclaims, above, as if fully set forth herein.

REPLY: No response is required to the general reallegation and incorporation by reference of Paragraphs 1-29 of the Counterclaims. To the extent a response is required, Plaintiffs hereby incorporate by reference their responses to Paragraphs 1-29.

COUNTERCLAIM:

31. The manufacture, use, sale, offer for sale, or importation of Milnacipran Hydrochloride tablets that are the subject of Mylan Pharms.' ANDA No. 205-367 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '220 Patent.

REPLY: Denied.

COUNTERCLAIM:

32. Mylan and Forest have adverse legal interests, and there is a substantial controversy between Mylan and Forest of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '220 Patent. Therefore, a present, genuine, and justiciable controversy exists between Mylan and Forest regarding, *inter alia*, the infringement of any valid or enforceable claim of the '220 Patent.

REPLY: Plaintiffs admit that Mylan and Forest have adverse legal interests and that a substantial controversy exists between Mylan and Plaintiffs concerning the infringement of the '220 patent. Plaintiffs deny the remaining allegations of Paragraph 32.

COUNTERCLAIM:

33. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Milnacipran Hydrochloride tablets that are the subject of Mylan Pharms.' ANDA No. 205-367 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '220 Patent.

REPLY: Denied.

COUNTERCLAIM:

34. Mylan re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Defenses and Counterclaims, above, as if fully set forth herein.

REPLY: No response is required to the general reallegation and incorporation by reference of Paragraphs 1-33 of the Counterclaims. To the extent a response is required, Plaintiffs hereby incorporate by reference their responses to Paragraphs 1-33.

COUNTERCLAIM:

35. The manufacture, use, sale, offer for sale, or importation of Milnacipran Hydrochloride tablets that are the subject of Mylan Pharms.' ANDA No. 205-367 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '110 Patent.

REPLY: Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 35.

COUNTERCLAIM:

36. Mylan and Forest have adverse legal interests, and there is a substantial controversy between Mylan and Forest of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the non-infringement of the '110 Patent. Therefore, a present, genuine, and justiciable controversy exists between Mylan and Forest regarding, *inter alia*, the infringement of any valid or enforceable claim of the '110 Patent.

REPLY: Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 36.

COUNTERCLAIM:

37. Mylan is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of the Milnacipran Hydrochloride tablets that are the

subject of Mylan Pharms.' ANDA No. 205-367 have not infringed, do not infringe, and would not, if marketed, infringe any valid and/or enforceable claim of the '110 Patent.

REPLY: Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 37.

COUNTERCLAIM:

38. Mylan re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Defenses and Counterclaims, above, as if fully set forth herein.

REPLY: No response is required to the general reallegation and incorporation by reference of Paragraphs 1-37 of the Counterclaims. To the extent a response is required, Plaintiffs hereby incorporate by reference their responses to Paragraphs 1-37.

COUNTERCLAIM:

39. An actual and justiciable case or controversy exists between Mylan and Forest as to invalidity of the '911 Patent.

REPLY: Plaintiffs admit that an actual and justiciable case or controversy exists between Mylan and Plaintiffs concerning the validity of the '911 patent. Plaintiffs deny the remaining allegations of Paragraph 39.

COUNTERCLAIM:

40. The claims of the '911 Patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including but not limited to §§ 101, 102, 103 and 112.

REPLY: Denied.

COUNTERCLAIM:

41. As a direct and proximate result of Forest's assertion of the '911 Patent, Mylan has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

REPLY: Plaintiffs admit that a definite and concrete, real and substantial judicial controversy exists between Mylan and Plaintiffs concerning the infringement and validity of the '911 patent.

Plaintiffs deny the remaining allegations in Paragraph 41.

COUNTERCLAIM:

42. Mylan is entitled to a judicial declaration that the claims of the '911 Patent are invalid.

REPLY: Denied.

COUNTERCLAIM:

43. Mylan re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Defenses and Counterclaims, above, as if fully set forth herein.

REPLY: No response is required to the general reallegation and incorporation by reference of Paragraphs 1-42 of the Counterclaims. To the extent a response is required, Plaintiffs hereby incorporate by reference their responses to Paragraphs 1-42.

COUNTERCLAIM:

44. An actual and justiciable case or controversy exists between Mylan and Forest as to invalidity of the '342 Patent.

REPLY: Plaintiffs admit that an actual and justiciable case or controversy exists between Mylan and Plaintiffs concerning the validity of the '342 patent. Plaintiffs deny the remaining allegations of Paragraph 44.

COUNTERCLAIM:

45. The claims of the '342 Patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including but not limited to §§ 101, 102, 103 and 112.

REPLY: Denied.

COUNTERCLAIM:

46. As a direct and proximate result of Forest's assertion of the '342 Patent, Mylan has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

REPLY: Plaintiffs admit that a definite and concrete, real and substantial judicial controversy exists between Mylan and Plaintiffs concerning the infringement and validity of the '342 patent.

Plaintiffs deny the remaining allegations in Paragraph 46.

COUNTERCLAIM:

47. Mylan is entitled to a judicial declaration that the claims of the '342 Patent are invalid.

REPLY: Denied.

COUNTERCLAIM:

48. Mylan re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Defenses and Counterclaims, above, as if fully set forth herein.

REPLY: No response is required to the general reallegation and incorporation by reference of Paragraphs 1-47 of the Counterclaims. To the extent a response is required, Plaintiffs hereby incorporate by reference their responses to Paragraphs 1-47.

COUNTERCLAIM:

49. An actual and justiciable case or controversy exists between Mylan and Forest as to invalidity of the '220 Patent.

REPLY: Plaintiffs admit that an actual and justiciable case or controversy exists between Mylan and the Plaintiffs concerning the validity of the '220 patent. Plaintiffs deny remaining allegations of Paragraph 49.

COUNTERCLAIM:

50. The claims of the '220 Patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including but not limited to §§ 101, 102, 103 and 112.

REPLY: Denied.

COUNTERCLAIM:

51. As a direct and proximate result of Forest's assertion of the '220 Patent, Mylan has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

REPLY: Plaintiffs admit that a definite and concrete, real and substantial judicial controversy exists between Mylan and Plaintiffs concerning the infringement and validity of the '220 patent. Plaintiffs deny the remaining allegations in Paragraph 51.

COUNTERCLAIM:

52. Mylan is entitled to a judicial declaration that the claims of the '220 Patent are invalid.

REPLY: Denied.

COUNTERCLAIM:

53. Mylan re-asserts, re-alleges, and incorporates by reference each of the foregoing Paragraphs of its Defenses and Counterclaims, above, as if fully set forth herein.

REPLY: No response is required to the general reallegation and incorporation by reference of Paragraphs 1-52 of the Counterclaims. To the extent a response is required, Plaintiffs hereby incorporate by reference their responses to Paragraphs 1-52.

COUNTERCLAIM:

54. An actual and justiciable case or controversy exists between Mylan and Forest as to invalidity of the '110 Patent.

REPLY: Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 54.

COUNTERCLAIM:

55. The claims of the '110 Patent are invalid for failure to comply with one or more of conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq.*, including but not limited to §§ 101, 102, 103 and 112.

REPLY: Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 55.

COUNTERCLAIM:

56. As a direct and proximate result of Forest's assertion of the '110 Patent, Mylan has suffered, and is suffering, irreparable injury to its reputation and goodwill in an amount that cannot presently be ascertained and that cannot adequately be compensated by monetary relief alone. Accordingly, a definite and concrete, real and substantial, justiciable controversy exists between the parties, herein, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

REPLY: Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7,

2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 56.

COUNTERCLAIM:

57. Mylan is entitled to a judicial declaration that the claims of the '110 Patent are invalid.

REPLY: Plaintiffs deny there is an actual controversy between Mylan and Plaintiffs concerning the '110 patent because (1) Plaintiffs did not assert the '110 patent; (2) on November 8, 2013, Plaintiffs provided Mylan with a covenant not to sue on the '110 patent; and (3) on January 7, 2014, Mylan filed a Notice of Partial Dismissal of its Counterclaims directed to the '110 patent. Plaintiffs otherwise deny the allegations of Paragraph 57.

MYLAN'S PRAYER FOR RELIEF

Plaintiffs deny that Mylan is entitled to any of the relief requested in Mylan's Prayer for Relief, deny that Mylan is entitled to a jury trial, and respectfully request that the Court:

- (i) enter judgment on Mylan's counterclaims in favor of Plaintiffs, and against Mylan;
- (ii) deny Mylan any and all relief on its counterclaims, including but not limited to the relief sought in prayer for relief (a) – (l), inclusive;
- (iii) declare this case to be exceptional;
- (iv) award costs and attorney fees to Plaintiffs;
- (v) award such further relief as this Court deems just and proper; and

(vi) deny Mylan's request for a trial by jury.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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CERTIFICATE OF SERVICE

I hereby certify that on January 9, 2014, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on January 9, 2014, upon the following in the manner indicated:

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